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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/806,608

03/23/2004

Takashi Tokuyama

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JORDAN AND HAMBURG LLP
122 EAST 42ND STREET
SUITE 4000
NEW YORK, NY 10168

EXAMINER

KIM, JENNIFER M

ART UNIT

PAPER NUMBER

1628

MAIL DATE

DELIVERY MODE

11/20/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/806,608	Applicant(s) TOKUYAMA ET AL.	
	Examiner JENNIFER M. KIM	Art Unit 1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 13, 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 1-11 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12, 14-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The response filed August 13, 2009 have been received and entered into the application.

Response to Arguments

Applicants' arguments filed August 13, 2009 have been fully considered but they are not persuasive. Applicants argue that one of the important characteristic features of the components of Tadashi et al is that it contains both of two components: a "fibroblast collagenase production-promoting substance" and an "epidermal ceramide synthesis-promoting substance" as essential components. This is not persuasive because Applicants' composition of "a skin conditioner **containing**..." to be utilized in the instant method claims do not exclude other agents such as "epidermal ceramide synthesis promoting substance". Further, the composition disclosed by Tadashi et al teaches the same effective agent such as ethanolamine for the same treatment of dry skin with the amounts preferably 0.001 to 10% (see page 8) which encompasses Applicants' effective amounts disclosed in page 21 of the specification. Therefore, the claimed mechanism (e.g. conditioning epidermis, epidermal keratocytes, corneal layer restoration of the barrier and moisturization) by which the same active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects (treatment of chapped skin

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or dry skin) which would result from the claimed method. The patient, condition to be treated and the effect are the same. An explanation of why that effect occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

Applicants argue that the example in Figs. 51 and 55 and Test Example 16 on page 65-66 of the present specification shows moisture retention ability improving agents. This is not persuasive because such beneficial effect of retention of moisture by employment of the composition having the same active agents with the same effective amount for the same treatment (dry skin) is an expected and unavoidable mechanism result next to the employment of the composition disclosed by Tadashi et al. Applicants argue that only the materials which are actually used in the working Examples of Tadshi et al are "serine" (Example 1) or "silk fiber partial hydrolyzate" (Example 2) alone. This is not persuasive because disclosed examples and preferred embodiments in Tadashi et al do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 169 USPQ 423 (CCPA 1971). The mere fact that the preferred embodiment is a serine does not teach away from the broad disclosure which discloses, as indicated above that a composition comprising ethanolamine is useful for the treatment of dry skin. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

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In view of the above Office Action of February 12, 2009 is deemed proper and asserted with full force and repeated herein to obviate applicants' claims.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 12 and 14-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tadashi et al. (JP 10001410) of record (see enclosed translation).

Tadshi et al. teach a cosmetic composition comprising fibroblast collagen production-stimulating substance such as ethanolamine having excellent in a skin ageing -preventing effect. Tadashi et al. teach that the composition can enhance the rotation of collagen metabolism. (abstract). Tadashi et al. teach the effective amount of ethanolamine to be employed in the composition as 0.001 to 10%. ([0014]). Tadashi et al. teach that the composition can be employ to improve dry skin conditions. [0020].

With regard to mechanism (e.g. conditioning epidermis, epidermal keratocytes, corneal layer restoration of the barrier and moisturization) by which the same active ingredient gives the pharmacological effect does not alter the fact that the compound has been previously used to obtain the same pharmacological effects (treatment of chapped skin or dry skin) which would result from the claimed method. The patient, condition to be treated and the effect are the same. An explanation of why that effect

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occurs does not make novel or even unobvious the treatment of the conditions encompassed by the claims.

None of the claims are allowed.

THIS ACTION IS MADE FINAL. Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Communication

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER M. KIM whose telephone number is (571)272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on 571-272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JENNIFER M KIM/
Primary Examiner, Art Unit 1617

Jmk
November 18, 2009